



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Cirillo, P., et al
U.S. Appln. No. : 10/789,354
Confirmation No. : 9059
U.S. Filing Date : February 27, 2004
Title of Invention : Cytokine Inhibitors
Attny. Docket No. : 9/276

) Art Unit: 1625
) Examiner: Desai, Rita

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

August 18, 2005

TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

- A statement as specified in 37 C.F.R. §1.97(e) [see below]; or
- The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

1.97(e).

Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

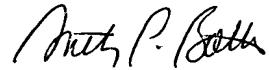
The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Respectfully submitted,



Anthony P. Bottino
Attorney for Applicant(s)
Reg. No. 41,629

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877
Tel: (203) 791-6764

Certificate of Mailing

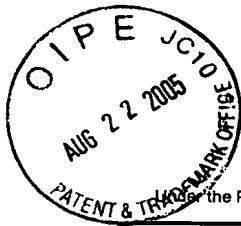
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner For Patents
P. O. Box 1450
Alexandria, VA 22313-1450

on August 18, 2005.



Anthony P. Bottino, Reg. No. 41,629



PTO/SB/08b (08-03)
Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

4

Complete if Known	
Application Number	10/789,354
Filing Date	2/27/2004
First Named Inventor	Pier Francesco CIRILLO
Art Unit	1625
Examiner Name	Rita J. Desai
Attorney Docket Number	9/276

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Tumor Necrosis Factor Inhibitors"; Early Alert Report, Fall 2000	
		van HEEL, D. A ET AL; "Inflammatory bowel disease is associated with a TNF polymorphism that affects an interaction between the OCT1 and NF- κ B transcription factors"; Human Molecular Genetics (2002): 1281-1289	
		WEBB, G. R., ET AL; "Chondrocyte tumor necrosis factor receptors and focal loss of cartilage in osteoarthritis"; Osteoarthritis and Cartilage, 1997, 5, 427-437	
		RAINE, C. S. ET AL; "Multiple sclerosis: expression of molecules of the tumor necrosis factor ligand and receptor families in relationship to the demyelinated plaque"; Rev. Neurol. (Paris) 1998, 154, 577-585	
		MA, J. J. ET AL; "Genetic Contribution of the Tumor Necrosis Factor Region in Guillain-Barré Syndrome"; Annals of Neurology, 1998, 44, 815-818	
		CHODOROWSKA, C. ET AL; "Plasma concentrations of IFN-gamma and TNF-alpha in psoriatic patients before and after local treatment with dithranol ointment"; J. Eur. Acad. Dermatology And Venereology, 1998, 10, 147-151	
		NAGLER, A. ET AL; "Dysregulation of inflammatory cytokines in unrelated bone marrow transplantation"; Cytokines, Cellular & Molecular Ther., 1998, 4, 161-167	
		ROBAK, E., "Association of Interferon gamma, Tumor Necrosis Factor alpha and Interleukin 6 Serum Levels with Systemic Lupus Erythematosus Activity"; Archivum Immunologiae et Therapiae Experimentalis, 1998, 46, 375-380	
		TASHIRO, H. ET AL; "Role of cytokines in the pathogenesis of restenosis after percutaneous transluminal coronary angioplasty"; Coronary Artery Disease, 12: 107-113	
		BROWN, G. R. ET AL; "Lymphoid Hyperplasia, CD45RBhigh to CD45RBlow T-cell imbalance, and suppression of Type I diabetes mellitus result from TNF blockade in NOD-NOD-scid adoptive T cell transfer"; Diabetologia, 1998, 41, 1502-1510	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/789,354
				Filing Date	2/27/2004
				First Named Inventor	Pier Francesco CIRILLO
				Art Unit	1625
				Examiner Name	Rita J. Desai
Sheet	2	of	4	Attorney Docket Number	9/276

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
		SOLTYS, J. ET AL; "Modulation of Endotoxin- and Enterotoxin-Induced Cytokine Release by In Vivo Treatment with beta-(1,6)-Branched beta-(1,3)-Glucan"; Infection and Immunity, 1999, 244-252				
		BJUGSTAD, K. B. ET AL; "Preventive actions of a synthetic antioxidant in a novel animalmodel of AIDS dementia1"; Brain Research, 1998, 795, 349-357				
		CHOU, R. C. ET AL; "Adrenergic regulation of macrophage-derived tumornecrosis factor-alpha generation durng a chronic polyarthritis pain model"; J. Neuroimmunol., 1998, 82, 140-148				
		MUELLER, G. ET AL; "Is Cytokine Expression Responsible for Differences Between Allergens and Irritants?"; American J. of Contact Dermitis, Vol. 7, No. 3 (September), 1996, 177-184				
		ELHAGE, R. ET AL; "Differential Effects of Interleukin-1 Receptor Antagonist and Tumor Necrosis Factor Binding Protein on Fatty-Streak Formation in Apolipoprotein E-Deficient Mice"; Circulation, 1998, 97:242-244				
		RYFFEL, B. ET AL; "Failure to induce anti-glomerular basement membrane glomerulonephritis in TNFalpha/beta deficient mice"; Int. J. Exp. Path., 1998, 79, 453-460				
		IMITSUI, Y. ET AL; "The expression of proinflammatory cytokine mRNA in the sciatic-tibial nerve of ischemia-reperfusion injury"; Brain Research, 844 (1999), 192-195				
✓		LI, D. ET AL, "Kinetics of tumor necrosis factor alpha in plasma and the cardioprotective effect of a monoclonal antibody to tumor necrosis factor alpha in acute myocardial infarction" Amer. Heart Journal..1999..137..1145-1152				
		YEH, F. L. ET AL, "Changes in serum tumour necrosis factor-alpha in burned patients"; Burns, 1997, 23, 6-10				
		RENZETTI, L. M. ET AL; "Ro 45-2081. a TNF receptor fusion protein, prevents inflammatory responses in the airways"; Inflamm. Res. 1997, 46, Suppl. 2, S143-S144				

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/789,354
				Filing Date	2/27/2004
				First Named Inventor	Pier Francesco CIRILLO
				Art Unit	1625
				Examiner Name	Rita J. Desai
Sheet	3	of	4	Attorney Docket Number	9/276

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
		LEMAY, S. ET AL; "Prominent and Sustained Up-regulation of gp130-Signaling Cytokines and of the Chemokine MIP-2 in Murine Renal Ischemia-Reperfusion Injury"; Transplantation, Vol. 69, No. 5, (2000), 959-963		
		BOERJESSON, A. ET AL; "TNF-alpha stimulates alveolar liquid clearance during intestinal ischemia-reperfusion in rats"; Am. J. Physiol. Lung Cell. Mol. Physiol., (2000) 278:L3-L12		
		KUROKOUCHI, K. ET AL; "TNF-alpha Increases Expression of IL-6 and ICAM-1 Genes Through Activation of NFkB in Osteoblast-like ROS17/2.8 Cells"; J. Bone and Mineral Res., 1998, 13, 1290-1299		
		HIGHAM, M. A. ET AL; "Tumour necrosis factor-alpha gene promoter polymorphism in chronic obstructive pulmonary disease"; Eur. Respir J. 2000, 15:281-284		
		TAKABATAKE, N. ET AL; "The Relationship between Chronic Hypoxemia and Activation of the Tumor Necrosis Factor-alpha System in Patients with Chronic Obstructive Pulmonary Disease"; Am. J. Respir. Crit. Care Med., Vol. 161, 2000, 1179-1184		
		LEE, T. H.; "Cytokine networks in the pathogenesis of bronchial asthma: implications for therapy"; J. of the Royal Coll. of Phys. of London, Vol. 32, No. 1, Jan/Feb. 1998; 56-64		
		LIPTON, J. M. ET AL; "Peptide Modulation of Inflammatory Processes within the Brain"; Neuroimmunomodulation, 1998, 5, 178-183		
		BRANGER, J. ET AL; "Anti-Inflammatory Effects of a p38 Mitogen-Activated Protein Kinase Inhibitor During Human Endotoxemia"; J. Immunol. 2002, 168: 4070-4077		
		VISCARDI, R. M. ET AL; "Inflammatory Cytokine mRNAs in Surgical Specimens of Necrotizing Enterocolitis and Normal Newborn Intestine"; Pediatric Pathol. And Lab. medicine, 1997, 17, 547-559		
		PARIS, M. M. ET AL; "The Effect of Interleukin-10 on Meningeal Inflammation in Experimental Bacterial Meningitis"; J. Infectious Dis. 1997, 176, 1239-1246		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Application Number</i>	10/789,354
				<i>Filing Date</i>	2/27/2004
				<i>First Named Inventor</i>	Pier Francesco CIRILLO
				<i>Art Unit</i>	1625
				<i>Examiner Name</i>	Rita J. Desai
<i>(Use as many sheets as necessary)</i>		Sheet		Attorney Docket Number	9/276
4		of	4		

NON PATENT LITERATURE DOCUMENTS

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.